

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO. 135 FILING DATE 12/08/93

RENDO

FIRST NAMED INVENTOR

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EXAMINER

ART UNIT

PAPER NUMBER

1807

#13

DATE MAILED:

04/29/96

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/157,195	Applicant(s) HENCO ET AL.
Examiner PAUL B. TRAN	Group Art Unit 1807



Responsive to communication(s) filed on Oct 20, 1995

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 67-108 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 67-108 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Part III DETAILED ACTION

1. The examiner acknowledges the receipt of Applicant's Amendment, Paper No. 12, filed October 20, 1995. Claims 1-26 and 39-66 have been cancelled by Applicant; new Claims 67-108 are added and pending before the examiner.
2. Regarding the oath, the examiner agrees with Applicant that a new oath for the instant application is not required because it can be identified by its PCT number, which is included in the oath. The objection to the oath is hereby withdrawn.
3. The examiner notes that Applicant did not follow the suggestion of the examiner regarding the arrangement of the contents in the specification.
4. The objection to the Abstract of the Disclosure is moot in view of the amended version of the Abstract. The objection is hereby withdrawn.
5. The rejection of claims 1-26 and 39-54 under 35 U.S.C. § 112, second paragraph, is moot in view of Applicant's cancellation of the claims. The rejection is hereby withdrawn.
6. The rejections of claims 5 and 49 under 35 U.S.C. § 112, fourth paragraph, are moot in view of Applicant's cancellation of the claims. The rejections are hereby withdrawn.

New Grounds of Objection & Rejection

7. Claims 67-108 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite because of the language "interacts." It is unclear as to what is

encompassed by said language, e.g. does it mean that the probe intercalates with or hybridizes to the amplified nucleic acid?

8. Claim 58 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is vague and indefinite because it is unclear as to the length of the nucleic acid portion of the probe.

9. Claims 76-78 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite because, in claim 76, line 4, there is missing a limitation following "nucleic acid to be."

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

Claim 69 is recited to have a limitation wherein "the measurable signal is detected" by several mechanisms as recited in the claim. This is new matter because the original specification does not so disclose; but rather, it teaches that, "the nucleic acid denaturation process initiated by the gradient

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is detected" using the same mechanisms that are recited in the claim (see page 5, second full paragraph).

Claim 69 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

11. The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

Claim 72 is recited to have a nucleic acid standard which is homologous to the analyzed nucleic acid, except for at least one point mutation. This is new matter because the original specification does not teach that large a scope as recited in the claim; rather, the specification teaches that the point mutation "lies in a sequence region of lowest stability" (See page 6, first full paragraph; and claim 6).

Claim 72 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

12. The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

Claim 75 is recited to have the analysis to be "determined either attached to the solid phase or within the homogenous phase." This is new matter because the original specification does not teach the latter; but rather it teaches that the determination is done "at the solid phase support or within the free solution" (See page 7, first full paragraph).

Claim 75 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

13. The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

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Claims 80-85 are recited to have the stable double bond linked to another position on the oligo- or polynucleotide by "excitation-effect emitting of electromagnetic radiation." This is new matter because the original specification does not teach that mechanism, but rather, it only teaches that the linking is done "through the action of electromagnetic waves" (Claim 14).

Claims 80-85 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

14. The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

Claims 93-96 are recited to have the probe having "at least one non-naturally occurring chemical structure element." This is new matter because the original specification does not teach such a probe.

Claims 93-96 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

15. Claims 67-108 are free of prior art.

16. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE

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MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

17. Any inquiry concerning this communication or those earlier from the examiner should be directed to Paul B. Tran, Ph.D., whose telephone number is (703) 308-4040.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose phone number is (703) 308-0196.

Paper related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

Paul B. Tran, Ph.D.
Art Unit 1807
4/26/96


W. GARY JONES
SUPERVISORY PATENT EXAMINER
GROUP 1800

4/27/96